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COMMENT
COSTS, NORMS, AND INERTIA: AVOIDING AN ANTICOMMONS FOR PROPRIETARY RESEARCH TOOLS +

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A decade ago the scientific community was sounding alarm bells about the impact of intellectual property on the ability of scientists to do their work.[1] Protracted negotiations over access to patented mice[2] and genes,[3] scientific databases,[4] and tangible research materials[5] all pointed toward the same conclusion: that intellectual property claims were undermining traditional sharing norms to the detriment of science. Michael Heller and I highlighted one dimension of this concern: that too many intellectual property rights in 'upstream' research results could paradoxically restrict 'downstream' research and product development by making it too costly and burdensome to collect all the necessary licenses.[6]

 I have previously published a more extensive analysis of the literature discussed in this paper at Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUSTON L. REV. 1059 (2008).

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[1] See, eg, NATIONAL RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY (1997); Report of the National Institutes of Health (NIH) Working Group on Research Tools (1998), available at <http://www.nih.gov/news/researchtools/index.htm>; Donald Kennedy, *Enclosing the Research Commons*, 294 SCIENCE 2249 (2001).

[2] Eliot Marshall, *NIH, DuPont Declare Truce in Mouse War*, 281 SCIENCE 1261 (1998); Eliot Marshall, *DuPont Ups Ante on Use of Harvard's Oncomouse*, 296 SCIENCE 1212 (2002); Sam Jaffe, *Ongoing Battle over Transgenic Mice*, THE SCIENTIST (July 19, 2004) at 46–47.

[3] Eliot Marshall, *Companies Rush to Patent DNA*, 275 SCIENCE 780 (1997); Michael Balter, *Transatlantic War Over* BRCA1 *Patent*, 292 SCIENCE 1818 (2001).

[4] AAAS Resolution, Statement on Intellectual Property Protection for Databases (1997), available at <http://archives.aaas.org/docs/resolutions.php?doc_id=446>.

[5] Eliot Marshall, *Need a Reagent? Just Sign Here*, 278 SCIENCE 212 (1997).

[6] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998). See also Carl Shapiro, *Navigating the Patent*

Since that time numerous empirical studies have sought to measure the impact of intellectual property on research scientists,[7] and found fewer impediments to academic research than policymakers may have projected on the basis of early salient controversies.[8] Outside the field of genetic testing,[9] most scientists report no difficulties in attempting to acquire IP-protected technologies, and only a small percentage report significant delays in research or having to abandon a project because of IP. Even in fields characterized by extensive patenting, many academic researchers seem to be either oblivious to the patents they might be infringing or unconcerned about potential infringement liability. More significant to researchers than patents as such have been restrictions on access to materials and data, such as requirements for institutional assent to the terms of materials transfer agreements.[10]

Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in INNOVATION POLICY AND THE ECONOMY 119–50 (A. Jaffe & J. Lerner eds., 2000).

[7] See John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285–340 (W. M. Cohen & S. Merrill eds. 2003) (hereinafter Walsh/Arora/Cohen *Effects*); John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, 299 SCIENCE 1021 (2003); John P. Walsh, Wesley M. Cohen, & Charlene Cho, *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RESEARCH POLICY 1184 (2007) (hereinafter Walsh/Cohen/Cho, *Where Excludability Matters*); John P. Walsh, Charlene Cho & Wesley Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005) (hereinafter *View from the Bench*); Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, in INNOVATION POLICY AND ECONOMICS 1–30 (8th ed. 2008) (hereinafter Cohen & Walsh, *Real Impediments*); OECD, GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES EVIDENCE AND POLICIES 45–49 (2002) (hereinafter OECD Genetic Inventions); Joseph Straus, Henrik Holzapfel & Matthias Lindenmeir, *Genetic Inventions and Patent Law, An Empirical Survey of Selected German R & D Institutions* (2004) (hereinafter Straus/Holzapfel/Lindenmeir); AAAS PROJECT ON SCIENCE AND INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST, INTERNATIONAL INTELLECTUAL PROPERTY EXPERIENCES: A REPORT OF FOUR COUNTRIES (2007), available at <http://sippi.aaas.org/Pubs/SIPPI_Four_Country_Report.pdf> (hereinafter 'SIPPI Report'); Dianne Nicol & Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003), available at <http://www.law.unimelb.edu.au/ipria/publications/workingpapers/BiotechReportFinal.pdf> (hereinafter Nicol & Nielsen).

[8] See Timothy Caulfield, Robert M. Cook-Deegan, F. Scott Kieff & John P. Walsh, *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091 (2006).

[9] The empirical record suggests that patents present greater obstacles to both research and clinical care in the DNA diagnostic field. See Mildred K. Cho, Samantha Illangasekare, Meredith A. Weaver, Debra G.B. Leonard, & Jon F. Merz, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3–8 (2003); Jon F. Merz, Antigone G. Kriss, Debra G.B. Leonard & Mildred Cho, *Diagnostic Testing Fails the Test*, 415 NATURE 577 (2002). For a description of problems in negotiating for patent licenses necessary to conduct particular genetic tests, see Sirpa Soini et al., *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues*, 16 EUR. J. OF HUMAN GENETICS S10, S15–S16 (2008).

[10] This finding is consistent with my own earlier observation, based on an investigation conducted for the NIH Working Group on Research Tools a decade ago, that low value transactions are more likely to fail than high value transactions. See Rebecca S. Eisenberg, *Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?*, in EXPANDING THE BOUNDS OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY (R. Dreyfuss, H. First & D. Zimmerman eds., 2001).

In one survey, 19% reported that their most recent request for materials was denied,[11] and many reported that, in the past two years, failure to receive requested materials led to significant delays and even to abandonment of projects. Scientists are far more likely to encounter obstacles in their efforts to gain access to materials and unpublished data than they are to encounter patent enforcement.

Two papers in this volume review and analyze these findings.[12] Wesley Cohen and John Walsh, who carried out some of the most prominent of the underlying studies, explain the difference between patents, on one hand, and materials or data, on the other hand, largely in cost-benefit terms, citing the relative ease of excluding competitors from access to research inputs that cannot be readily replicated by other researchers and the relative costliness of tracking down patent infringers and suing them.[13] Nonetheless, they find evidence of a sharing norm that retains some vitality in the willingness of most researchers to share data and materials with their competitors even when it is costly for them to do so.[14] Observing higher rates of withholding materials in their own data than in an earlier study,[15] they suggest an explanation for the apparent decline in sharing that has nothing to do with commercial practices: perhaps higher levels of NIH funding are to blame, because they make exclusionary practices more advantageous as scientists compete more vigorously for larger grants.[16] At the same time, they see exclusionary practices as having positive incentive effects on the scientists who develop the resources and worry that NIH policies designed to compel sharing might dampen scientific progress by limiting these incentives.[17]

Katherine Strandburg reviews the same studies and offers a somewhat different explanation.[18] Strandburg sees the emergence of an 'ignoring patents' norm alongside the traditional sharing norm in science.[19] Noting more problems with the transfer of tangible materials, she suggests that the costs of sharing tangible materials make it more difficult to enforce a sharing norm for these resources.[20]

[11] Walsh, Cohen & Cho, *View from the Bench*, n. 7 above, at 2002.

[12] Wesley M. Cohen & John P. Walsh, *Access—or not—in Academic Biomedical Research*, Chapter 1 in this volume (hereinafter Cohen & Walsh chapter); Katherine J. Strandburg, *Norms and the Sharing of Research Materials and Tacit Knowledge*, Chapter 4 in this volume (hereinafter Strandburg chapter).

[13] Cohen & Walsh chapter, n. 12 above, at 25–33, 36.

[14] Ibid. at 34–7. Costs of sharing include the risk of losing future priority of discovery to a competitor as well as the immediate tangible costs of duplicating and providing materials. Ibid. at 31.

[15] Cohen & Walsh, *Real Impediments*, n. 7 above, at 15.

[16] Ibid. at 20.

[17] Cohen & Walsh chapter, n. 12 above, at 38.

[18] Strandburg chapter, n. 12 above; see also Katherine J. Strandburg, *User Innovator Community Norms at the Boundary Between Academic and Industrial Research*, 77 FORDHAM L. REV. (forthcoming 2009), available at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1413229> (hereinafter Strandburg, *Community Norms*).

[19] Ibid. at 118–20, Strandburg chapter, n. 12 above, at 2.

[20] Ibid. at 17–20.

Her normative story rests on an account of the preferences of academic scientists as rational actors, including a preference to learn the results of the collective research project.[21] In contrast to Cohen and Walsh, she assumes that researchers would be adequately motivated to invest in tool development by their need for tools to use in their own research, even without the benefits of exclusivity, and that increased sharing would therefore be unequivocally good for science.[22] She therefore proposes mechanisms to promote the sharing of research materials and to reduce the private payoffs of exclusivity.

The cost-benefit account and the norms account are not entirely distinct. Costs and benefits lurk behind norms, and norms factor into the costs and benefits of actions that violate or conform to those norms. In the end, the most striking differences between Cohen & Walsh on one hand and Strandburg on the other reside not in their explanations of the data but in their assumptions on matters that the data do not illuminate. Nonetheless, the two accounts have somewhat different implications for understanding the role of transaction costs and the potential for an anticommons arising in the exchange of research tools.

I. Cost-Benefit Analysis

The cost-benefit account offers a straightforward explanation for the observation that exchanges of materials are more likely to give rise to research-impeding transaction costs and bargaining breakdowns than exchanges driven by patent rights.

As a matter of law, a user needs to get permission from the patent owner before using a patented invention. But as a matter of practice, both owners and infringers routinely ignore patents in the context of upstream research. Would-be users thus readily gain access to patented technology without having to engage first in costly bargaining, a fact that minimizes the risk of an anticommons arising from a proliferation of patents alone.

Cohen and Walsh distinguish patent rights from what they call 'practical excludability.'[23] With or without a patent, a scientist or institution may control access to a resource, such as a large private database or a transgenic mouse. Those in control of such a resource hold the practical power to force other users to enter into an agreement before they will share it. Sometimes practical excludability and

[21] Strandburg argues that 'the pervasiveness of the disregard for patents, its justification in normative terms ... the distinction between using a tool in research and "making a profit," the use of reputational and shunning penalties to enforce forbearance and sharing, and the involvement of community organizations and high-status members as "norm entrepreneurs" in promoting it suggest that the "ignore research tool patents" is a positive social norm enforced within the community of academic and industrial researchers.' Ibid. at 121.

[22] Ibid. at 11, 19.

[23] Cohen & Walsh, *Real Impediments*, n. 7 above.

patent protection may both be present, as in the case of patented transgenic mice.[24] But sometimes users have the capacity to duplicate patented inventions in their own laboratories without the cooperation of the patent owner,[25] and sometimes users need the cooperation of owners before they can gain access to unpatented materials and data.

Practical excludability has three notable attributes. First, for practical excludability to exist, the resource must be costly for users to recreate on their own. If users are able to duplicate the resource at reasonable cost in their own laboratories, they may not even become aware of purely legal obstacles such as patents. Strandburg explains that it may be more costly for users to duplicate materials because the materials embody considerable tacit knowledge about how to produce them or because of the importance of standardization for the research.[26] The same may be true of new methods or data. If it is costly for users to recreate the resource, it may also be costly for the owner to provide it,[27] although this is not a necessary feature of practical excludability. The costliness of sharing may make owners less willing to share; on the other hand, owners may be able to exchange the practically excludable resource for value that helps defray its costs.[28] As long as it is cheaper for the owner to share the resource than it is for the user to recreate it, there are potential gains from exchange that stand to be dissipated through transaction costs or lost through bargaining breakdowns.

Second, practical excludability requires that the owner be able to exclude users from the resource at low cost. This is an important distinction between patents and practical excludability. Enforcement of a patent is a high cost endeavor; failure to share materials and data may require little or no effort on the part of the owner. Exclusion becomes more costly if the owner needs to share the resource to secure

[24] David Mowery and Arvids Ziedonis have examined Materials Transfer Agreements (MTAs) at the University of Michigan and found that they are often complements to patents rather than substitutes for patents. David C. Mowery & Arvids Z. Ziedonis, *Academic Patents and Materials Transfer Agreements: Substitutes or Complements?*, 32 J. TECHNOL. TRANSFER 157 (2007).

[25] It is tempting to speculate that the patent law requirement for an enabling disclosure of how to make and use the invention, 35 U.S.C. § 112, forces inventors to codify their inventions and thereby puts researchers in possession of the invention without the need for further consultation with the inventor. But it seems from the studies reviewed herein that many researchers are infringing patents that they are not aware of, suggesting that they are learning how to make and use these inventions from sources other than patent disclosures.

[26] Strandburg chapter, n. 12 above, at 17.

[27] It may consume costly materials and the time of skilled laboratory personnel to reproduce tangible materials and to ship them off, or to train the user to produce the materials independently. See ibid. at 20–29. Even in the case of data, it may be costly for the owner to provide access in a form that is readily usable by others or to explain how to use a database. Moreover, as Cohen and Walsh elaborate, sharing a resource with competitors may deprive the owner of a competitive advantage in future research, at the cost of losing future priority of discovery and attendant future rewards. Cohen & Walsh, *Real Impediments*, n. 7 above, at 4–7.

[28] Payment may take many forms, including cash, acknowledgement in publications, collaboration on future research, or license rights to future discoveries.

patents or other rewards, or to avoid reputational penalties. When it is cheap for owners to exclude users, exclusion is more likely.

Third, when it is costly for users to create the resource on their own, and cheap for owners to exclude users, the burden of inertia rests on the user to overcome transaction costs before proceeding with the use. This is another important distinction between patents and practical excludability. If a patent is the only obstacle to use of a technology, the burden of inertia rests on the patent owner to detect and stop the infringing activity, generally after it is under way. The patent owner has a legal remedy, but this remedy is not self-executing. Infringement litigation is costly and fraught with risks. The cost and risk may seem worthwhile if market exclusivity in a lucrative product is at stake, but if the user is an academic researcher who is not close to developing a commercial product, the owner may conclude that the costs of enforcement do not justify the potential gains. The higher the costs of enforcement, the less likely enforcement becomes. In this environment, researchers may feel that it is generally safe to proceed without a license, even when they are aware of the patents.

Compare the position of a researcher who wishes to use a tangible research tool that she cannot readily duplicate in her own laboratory. If it is cost-prohibitive to duplicate the tool, the burden of inertia rests on the user to persuade the party in control to agree to share it before proceeding with the use. The owner doesn't have to bring an infringement action in order to force researchers to pay, but can sit back and wait for users to seek access and then bargain over terms. The tool may or may not be covered by a patent, and the researcher who seeks access may or may not be aware of the patent if it exists. The obstacle that academic researchers take note of is not likely to be a patent, but a restriction on access to something that is costly to duplicate without a license. The need for *ex ante* cooperation from the owner requires the researcher to incur transaction costs before proceeding in a way that the remote future possibility of infringement liability does not.

This highlights an interesting dimension to the anticommons problem that Heller and Eisenberg did not address: the burden of inertia matters in predicting the likelihood of use in the presence of significant transaction costs. When the burden of inertia to clear rights in advance is on users—as it is when researchers seek access to materials or data from someone else—high transaction costs work to the detriment of users, creating a risk of underuse. The user must incur these costs before using the resource, and if the transaction costs exceed the expected value of the use, it likely will not happen. But when the burden of inertia to enforce rights against infringers after the fact is on owners—as it is when users infringe patents—high transaction costs work to the detriment of owners, mitigating the risk of underuse. The more costly it is to enforce patents, the less likely it is that owners will go to the trouble, making it less risky for users to proceed without first bargaining for a license.

Of course, this dichotomous account of the burden of inertia is a simplified story that may not capture the nuances of every potential transaction. One can imagine

circumstances in which the party whom I have pictured as free of the burden of inertia—the unlicensed user in the case of patents or the owner of the resource in the case of practical excludability—is motivated to seek out a deal rather than to leave it up to the other party to make the first move. A patent infringer may fear legal liability and want to secure a license before proceeding further with R&D, even though the patent owner is so far unaware of the infringing activity or willing to ignore it for now. As for material transfers, some owners may affirmatively want to disseminate their materials for profit and be motivated to seek out potential users as customers, incurring transaction costs along the way rather than leaving the burden of inertia on would-be users. Moreover, the burden of inertia may shift as the situation unfolds. If the patent owner takes action to enforce the patent, the infringer may need to incur significant costs to respond. Even if the user makes the first move, an owner of materials who wants to enter into a lucrative transfer will need to incur transaction costs in order to get to that point. But despite the plausibility of these alternative scenarios, the recurring observation in multiple studies that negotiations over transfer of materials are more likely to block research than patents suggests that the simplified account holds true much of the time. The result is, on one hand, to mitigate the risk of an anticommons arising from a proliferation of patents alone and, on the other hand, to aggravate the risk of an anticommons arising from a proliferation of resources that are characterized by practical excludability.

For purposes of refining the anticommons hypothesis, what matters is that high transaction costs to clear property rights do not necessarily lead to inefficient underuse. Not every property right is like a padlock on a door that cannot be opened without first tracking down the owner and negotiating to get the key. Some property regimes put the burden on the owner to identify and pursue those who have gained access without permission. In such a regime, the costlier it is to enforce property rights, the less likely it is that enforcement will occur, and the safer it is to proceed without a license.

The burden of inertia may provide an adjustable mechanism for shifting the balance between *ex ante* incentives for innovation and downstream risks of an anticommons without changing the underlying property rights. Where the burden of inertia lies may appear at first to be mere happenstance—a fortuitous consequence of the cost of replicating a particular resource, or an inadvertent byproduct of the costs of enforcing legal rights in a society that cares about due process. But the burden of inertia can sometimes be adjusted as a design feature of property regimes. Legal proceedings may be elaborate or simple. Burdens of proof may be placed on plaintiffs or on defendants. The sheriff may lend owners a hand or leave them to fend for themselves.

Consider the case of patents. As noted, ordinarily the burden of inertia to enforce patents rests on patent owners. But in the case of patented drugs, Congress has shifted some of that burden from owners to infringers. Under the Drug Price Competition and Patent Term Restoration Act of 1984, sometimes known as the

Hatch-Waxman Act,[29] patent owners who seek to exclude generic competitors from the market are not limited to the slow and costly process of seeking a judicial remedy for infringement, but may use their patents to defer FDA approval of a generic version of a patented drug.[30] The statute requires the manufacturer of a generic version of a previously approved drug to certify to the FDA that its product does not infringe any valid patents, even if it otherwise meets the FDA's standards for approval.[31] If the generic manufacturer challenges the patent, the owner may file a lawsuit to establish that the patent is valid and infringed. But the owner need not await a judicial remedy to get relief. While the lawsuit is pending, and without evaluating its merits, the FDA will enter an automatic 30-month stay of approval of the generic product.[32] The net effect is similar to a preliminary injunction against the generic product, but without the usual burden on the patent owner to demonstrate a likelihood of success on the merits, irreparable harm, a balance of hardships in its favor, and impact on the public interest.[33] Although this enhanced benefit to patent owners gains leverage from a legal regime outside the patent system, it is hardly an inadvertent byproduct of FDA regulation. The statute explicitly directs FDA to consider patent protection and the status of infringement litigation in determining the effective date of product approval.[34] The result is a significant shift in the burden of inertia away from the patent owner.

A similar shift in the burden of inertia has occurred between copyright owners and creators of academic coursepacks as a consequence of judicial decisions holding commercial copy centers liable for making and selling photocopies of copyrighted materials for classroom use.[35] Although the copyright statute explicitly permits fair use of a copyrighted work, including 'reproduction in copies ... for purposes such as ... teaching (including multiple copies for classroom use),'[36] the courts have held that a for-profit copy center that makes such copies for sale to students is not entitled to claim fair use.[37] Fearing liability for infringement, many copy centers thereafter began requiring that professors obtain licenses to reproduce all copyrighted works before they would make copies of coursepacks. The result

[29] Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered provisions of 15 U.S.C., 28 U.S.C., and 35 U.S.C.) (hereinafter Hatch-Waxman Act).

[30] 15 U.S.C. §§ 355 (b), (c), (j).

[31] 15 U.S.C. § 355 (j).

[32] See, eg, *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003) (holding that Hatch-Waxman Act does not require FDA to review patents for validity and infringement).

[33] See, eg, *Sanofi-Synthelabo v. Apotex*, 470 F.3d 1368, 1374 (Fed. Cir. 2007) (reciting standards for preliminary injunction).

[34] 15 U.S.C. §§ 355 (b), (c), (j).

[35] See *Basic Books Inc. v. Kinko's Graphics Corp.*, 758 F. Supp. 1522 (S.D.N.Y. 1991), *Princeton University Press v. Michigan Document Services*, 99 F.3d 1381 (6th Cir. 1996).

[36] 17 U.S.C. § 107.

[37] 99 F.3d at 1389.

has been a dramatic shift in the burden of inertia from copyright owners onto professors who use their works in teaching materials.[38]

If policymakers were so inclined, they could find ways of shifting the burden of inertia from the owners of patents on research tools onto infringers of those patents. The studies reviewed herein suggest that academic researchers often get away with patent infringement,[39] and those who fear that patents could otherwise impede academic research might consider that a good thing. But suppose one believed, as Cohen & Walsh tentatively suggest,[40] that the lack of practical excludability prevents owners of research tool patents from receiving adequate compensation for their innovations from the researchers who use them.[41] One might try to lighten the burden of inertia on patent owners by making it easier for them to get preliminary injunctions against unauthorized use of their inventions in research. Or, one might borrow the power of federal research sponsors over grantees to facilitate enforcement by patent owners, much as Congress has borrowed the power of FDA over drugs to reduce the burden on owners of drug patents.[42] Research sponsors might, for example, require grantees to promise to exercise due diligence to avoid patent infringement, or to affirm that the work for which they seek funding will not infringe patents. They might also retain the right to suspend grant funding for patent infringers.

Of course, such a shift in the burden of inertia could aggravate the risk of an anticommons developing. If policymakers are more worried about creating an anticommons than they are about fortifying upstream R&D incentives, they might have quite the opposite impulse. Rather than making it cheaper to enforce patents, they might make it more costly. In fact, federal funding agencies have shown little political inclination to strengthen the hand of patent owners against their own grantees. Quite the contrary, NIH has instead used its influence as research sponsor to reduce transaction costs that impede access to proprietary research tools and to minimize the impact of patents on academic research.[43] After the Court of Appeals for the

[38] See, eg, Stanford University Libraries, Copyright & Fair Use, available at <http://fairuse.stanford.edu/Copyright_and_Fair_Use_Overview/chapter7/7-a.html>; University of Texas, Fair Use of Copyrighted Materials, available at <http://www.utsystem.edu/ogc/Intellectualproperty/COPYPOL2.HTM>.

[39] See nn. 7–11 above and accompanying text.

[40] See n. 17 above and accompanying text.

[41] For a defense of the importance of providing effective protection for research tool patents, see *Integra Lifesciences I, Ltd. v. Merck KgAA*, 496 F.3d 1334, 1338 (Fed. Cir. 2007) (Rader, J., dissenting in part and concurring in part). See also Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921 (2006) (arguing that exemptions from infringement liability should be narrowly construed).

[42] See nn. 29–34 above and accompanying text.

[43] See, eg, Dep't of Health & Human Serv., Nat'l Inst. Of Health, Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090 (Dec. 23, 1999); Memorandum of Understanding Between E.I. DuPont de Nemours & Co. and Public Health Service (July 1, 1999), available at <http://www.ott.nih.gov/pdfs/oncomouse.pdf> and Memorandum of Understanding Between DuPont Pharmaceuticals

Federal Circuit squarely held that nonprofit research in universities is not categorically exempt from infringement liability,[44] the National Academies of Science put a research exemption from patent infringement on its legislative agenda for patent law reform.[45]

Given the reported infrequency of patent enforcement against universities and academic researchers, it is interesting that the scientific community remains concerned about this issue.[46] Perhaps the institutional perspective of universities is different than the individual perspective of researchers as revealed in the reported studies.[47] Universities may feel little confidence that past patterns of nonenforcement of patents will continue indefinitely. Public universities appear for now to enjoy sovereign immunity from patent infringement actions,[48] but there are signs that the Supreme Court may be retreating from its prior robust concept of state sovereign immunity.[49] Patent infringement exposes both researchers and

and Public Health Service (July 1998), available at <http://www.ott.nih.gov/pdfs/cre-lox.pdf>; Dep't of Health & Human Serv., Nat'l Inst. Of Health, Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18413 (April 11, 2005).

The Supreme Court extended further protection from infringement liability for upstream research with its decision in *Merck v. Integra*, 545 U.S. 193 (2005), broadly construing a statutory exemption from infringement liability to cover industry-sponsored research in a university laboratory on a patented molecule. The statutory exemption was added as part of the Hatch-Waxman Act, n. 29 above, to permit clinical testing of generic versions of patented drugs during the patent term to facilitate prompt market entry thereafter, but the statutory language provides more broadly:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs ...

Hatch-Waxman Act § 202, codified at 35 U.S.C. § 271(e)(1). The statutory basis for the exemption was not that the research occurred in a university setting, but rather that it was related to the development and submission of information to the FDA, a condition that commercial research can more easily satisfy than academic research. 545 U.S. at 202, 206.

[44] *Madey v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002).

[45] STEPHEN A. MERRILL ET AL., A PATENT SYSTEM FOR THE 21ST CENTURY 82 (2004).

[46] See Association of American Universities et al., Comments on H.R. 1908 and S. 1145, The Patent Reform Act of 2007 (2007) at 5, available at <http://www.nacua.org/documents/PatentReformAct_Comments.pdf>.

[47] Studies of the impact of intellectual property on research scientists have relied heavily on surveys of working scientists rather than professionals engaged in technology transfer or freedom to operate. It is possible that these professionals know more than scientists about costs imposed on universities in dealing with demand letters from patent owners, for example.

[48] See *College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board*, 527 U.S. 666 (1999).

[49] For the robust version of sovereign immunity, see *Seminole Tribe v. Florida*, 517 U.S. 44 (1996); *Florida Prepaid v. Coll. Sav. Bank*, 527 U.S. 627 (1999); *Coll. Sav. Bank v. Fla Prepaid Postsecondary Educ. Expense Board*, 527 U.S. 666 (1999). For a critique of these decisions in the context of patent infringement by universities and a suggestion that the federal government should condition receipt of federal research funds on a waiver of sovereign immunity for patent infringement, see Jennifer Polse, *Holding the Sovereign's Universities Accountable for Patent Infringement after* Florida Prepaid *and* College Savings Bank, 89 CALIF. L. REV. 507 (2001). For recent evidence of possible retreat from the robust version of sovereign immunity, see *Cent. Virginia Cmty. Coll. v. Katz*, 546 U.S. 356 (2006) (holding that Congress has authority to abrogate state sovereign immunity in bankruptcy cases). The Supreme

institutions to risks of liability, but academic institutions have endowments that might make them more attractive targets of enforcement than individuals, and they may better appreciate the magnitude of the liability risk. Universities are generally risk-averse institutions, and they may find it challenging even to evaluate risks of patent infringement liability. Liability risks, as well as freedom to operate costs, increase with the number of relevant patents, which might tempt risk-averse institutions to curtail research in areas characterized by extensive patents. But traditions of academic freedom make it difficult for university administrators to control the behavior of scientists in order to control liability risks. Perhaps a research exemption that eliminates the risk seems like a good way out of this bind.

II. Sharing Norms

Katherine Strandburg offers a norms-based account of the lack of enforcement of patents in academic research.[50] According to this account, the research community has responded to a proliferation of patents in upstream research by adapting its traditional norms, which in the past called for sharing and not patenting, to permit patenting but also to call for ignoring patents in the context of university research.[51] She finds evidence that norms play a role in the dissemination of research tools in the efforts of prestigious scientific institutions, such as the National Academies of Science[52] and the National Institutes of Health,[53] to encourage sharing and to preserve freedom to operate for the scientific community, especially in the context of biomedical research. Empirical evidence suggests that universities have sought to abide by the guidelines established by these institutions in licensing their own patents.[54]

Court recently sought the views of the solicitor general on a petition for certiorari in a case that could call into question the scope of state sovereign immunity in the patent law context. *Biomedical Patent Mgmt. v. California*, 128 S. Ct. 2076, 170 L. Ed. 2d 792 (2008) (inviting the Solicitor General to file a brief expressing the views of the United States in a patent infringement action brought against the California Department of Health Services that was dismissed on sovereign immunity grounds), decision below at *Biomedical Patent Mgmt. v. California*, 505 F.3d 1328 (Fed. Cir. 2007).

[50] See Strandburg, *Community Norms*, n. 18 above.

[51] Ibid. at 114.

[52] See, eg, NATIONAL RESEARCH COUNCIL, FINDING THE PATH: ISSUES OF ACCESS TO RESEARCH RESOURCES (1999); NATIONAL RESEARCH COUNCIL, SHARING PUBLICATION-RELATED DATA AND MATERIALS: RESPONSIBILITIES OF AUTHORSHIP IN THE LIFE SCIENCES (2003); NATIONAL RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (2006).

[53] Principles and Guidelines for Recipients of NIH Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 24090 (Dec. 23, 1999), available at <http://ott.od.nih.gov/pdfs/64FR72090.pdf>, NIH Data Sharing Policy and Implementation Guidance (Mar. 5, 2003), available at <http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm>.

[54] Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31 (2006). See also *White Paper, In the Public Interest: Nine Points*

One difficulty with this account is that it is not obvious as a normative matter why the scientific community would embrace an 'ignore patents' norm that is more robust than its sharing norms for materials and data.[55] Strandburg suggests that it is more challenging for the scientific community to maintain sharing norms for these resources because it is more costly to share them and because there are greater benefits to be gained by not sharing.[56] Cohen and Walsh see evidence of a possible sharing norm for materials in the fact that, despite the costs of sharing and the benefits of not sharing, most requests for materials and data are fulfilled.[57] It is possible that patents lurk behind some instances of failure to share materials, and that withholding of patented materials pending completion of a materials transfer agreement functions as a low-cost means of enforcing rights to these inventions against academic researchers.[58] Further empirical work might help to illuminate what the relevant norms are, how they are enforced, and how much work they do.

The norms account has some explanatory power in understanding counterexamples in which patents have actually been enforced. To the extent that nonenforcement of patents depends on the operation of social norms, one might expect that those norms would be more effective among members of a close-knit, homogeneous community who share those norms and who interact with each other enough to anticipate reciprocal claims and feel vulnerable to reputational consequences if they depart from the norms.[59] Such community members know that in the next round the positions of owner and user may be reversed, making owners more likely to treat users as they would hope to be treated themselves. Conversely, one might expect less compliance with norms by outsiders or fringe members of the community who have fewer concerns about reputation and reciprocity.

This may help explain the limited traction of the 'ignore patents' norm in the context of genetically altered mice.[60] One firm, duPont, obtained dominant patent

to Consider in Licensing University Technology (March 6 2007) (hortatory statement signed on behalf of nine research universities and the American Association of Medical Colleges encouraging universities to license inventions in accordance with normative principles), available at <http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf>.

[55] Perhaps the relevant normative distinction has less to do with sharing than with norms and traditions of free inquiry, particularly in academic research, which is where all scientists begin their careers. Hauling researchers into court to get them to stop their experiments may feel like an aggressive violation of their right of free inquiry, while failing to send off a transgenic mouse may seem more like failing to make a charitable contribution.

[56] Strandburg chapter, n. 12 above, at 17–19.

[57] Cohen & Walsh, *Real Impediments*, n. 7 above, at 18.

[58] In their study of materials transfer agreements at the University of Michigan, David Mowery and Arvids Ziedonis, find that the use of materials transfer agreements often precedes the filing of a patent application and increases the likelihood that the university will patent the invention. David C. Mowery & Arvids Z. Ziedonis, n. 24 above, at 167.

[59] Strandburg, *Community Norms* n. 18 above, at 41.

[60] In a series of papers Fiona Murray has described the impact of patenting on the dissemination of the oncomouse and the response of the scientific community to licensing terms offered by duPont. Fiona Murray, *The Oncomouse That Roared: Resistance and Accommodation to Patenting in Academic*

rights as the exclusive licensee of Harvard University on both oncomice (ie, mice that have been genetically engineered to be susceptible to cancer) and cre-lox technology for creating 'knockout' mice (ie, mice in which certain genes are deleted in specific tissues). Oncomice and knockout mice are both important research tools. DuPont offered the mice to researchers on terms that provoked outrage in the academic community, including a prohibition on any further sharing or breeding of the mice, annual disclosure to duPont of research results, and a grant-back to duPont of rights in any future discoveries arising from use of the mice.[61] Some scientists responded by willfully ignoring the patent while creating their own mice and lobbying their universities to refuse to sign the duPont agreement.[62] Mouse geneticists discussed strategic responses at scientific meetings, and the National Academy of Sciences held a workshop and published a report on the topic.[63] The Director of the National Institutes of Health became personally involved in negotiations with duPont.[64] After *four years* of high-level negotiations, duPont and NIH finally signed a Memorandum of Understanding that permitted academic scientists to use oncomice without cost for noncommercial purposes, but did not permit them to transfer the mice to scientists at other institutions without using a duPont MTA, nor to use them in industry-sponsored research.[65] These restrictions have proven to be an ongoing source of problems between duPont and the scientific community, even years after the NIH Memorandum of Understanding.[66]

Controversy over the licensing of these patents is sometimes presented as a clash between corporate and academic cultures.[67] But few corporate-academic interactions in biomedical research have been as protracted and difficult as this one. Perhaps duPont, whose core business is chemistry,[68] was less concerned about the traditional sharing norms of biomedical research than firms from the biopharmaceutical industry

Science (Working Paper 2006), available at <http://web.mit.edu/fmurray/www/papers/THE%20ONCOMOUSE%20THAT%20ROARED_FINAL.pdf> (hereinafter Murray, *The Oncomouse That Roared*); Fiona Murray, *Patenting Life: How the Oncomouse Patent Changed the Lives of Mice & Men* (Working Paper 2007), available at <http://www.bus.wisc.edu/insite/events/seminars/documents/Oncomouse_Chapter_Short_09242007.doc> (hereinafter Murray, *Mice and Men*).

[61] Murray, *Mice & Men*, n. 60 above, at 25.

[62] Ibid. at 27.

[63] See NATIONAL RESEARCH COUNCIL, SHARING LABORATORY RESOURCES: GENETICALLY ALTERED MICE (1994).

[64] Murray, *Mice & Men*, n. 60 above, at 31.

[65] Ibid.

[66] Eliot Marshall, *DuPont Ups Ante on Use of Harvard's OncoMouse*, 296 SCIENCE 1212 (2002); Sam Jaffe, *Ongoing Battle Over Transgenic Mice*, 18(14) THE SCIENTIST 46 (2004); Sasha Blaug, Colleen Chien, & Michael J. Shuster, *Managing Innovation: University-Industry Partnerships and the Licensing of the Harvard Mouse*, 22 NATURE BIOTECHNOLOGY 761 (2004).

[67] See Murray, *The Oncomouse That Roared*, n. 60 above, at 1 ('The Oncomouse is a prominent example of the increasingly common collision between two institutions—academic and commercial science.').

[68] For a history of R&D at DuPont, see DAVID A. HOUNSHELL & JOHN KENLY SMITH, JR., SCIENCE AND CORPORATE STRATEGY: DUPONT R&D 1902–1980 (1988).

that had more pervasive interactions with academic biomedical scientists. If the 'ignore patents' norm is more effective within the biomedical research community than it is between community members and nonmembers, the community may have reason to be concerned about the future. As biomedical research draws increasingly on research in other fields, such as information technology[69] and nanotechnology,[70] researchers may find themselves at greater risk of trespassing upon patents held by institutions outside the biomedical research community who feel less constrained to observe the community's sharing norms.

Community norms might also be ineffective at deterring infringement actions against universities by disgruntled faculty members. We have already seen an example in the case of *Madey v. Duke*.[71] Patents have so far played a relatively small role in intra-academic disputes, but the patent infringement claim is the one that worked for Professor Madey, and it would not be surprising to see other unhappy professors play that card in the future. Although typically universities own the patents on inventions made by faculty, faculty members sometimes obtain patents on inventions that universities have elected not to pursue.[72] If the faculty member later leaves the institution under unhappy circumstances, that patent may be a valuable weapon in any ensuing legal dispute.[73] In the context of such disputes, aggrieved faculty members could be motivated to pursue a winning legal theory even though it is not cost-justified and violates traditional norms.

To the extent that the scientific community relies on sharing norms to forestall anticommons problems, one might wonder about the durability of those norms looking forward. Fiona Murray and Scott Stern have suggested that the impact of intellectual property on the scientific community may shift over time as legal rules

[69] See NIH, Recommendations of the Biomedical Information Science & Technology Initiative Implementation Group (2000), available at <http://www.bisti.nih.gov/bisti_recommendations.cfm>.

[70] See Kelly Y. Kim, *Research Training and Academic Disciplines at the Convergence of Nanotechnology and Biomedicine in the United States*, 25 NATURE BIOTECHNOLOGY 359–61 (2007); NIH Bioengineering Consortium, Nanoscience and Nanotechnology: Shaping Biomedical Research June 2000 Symposium Report, available at <http://www.becon.nih.gov/nanotechsympreport.pdf> (visited July 30, 2008).

[71] 307 F.3d 1351 (Fed. Cir. 2002). Professor Madey owned patents on laboratory equipment that he used to perform research at Duke University. After his relationship with Duke unraveled and Duke replaced him as principal investigator on a grant, Professor Madey sued on a variety of legal theories, including patent infringement. See Rebecca S. Eisenberg, *Patent Swords & Shields*, 299 SCIENCE 1018–19 (2003).

[72] If a university that is receiving federal funding does not elect to retain title to an invention, US law provides that 'the Federal agency may consider and after consultation with the [university] grant requests for retention of rights by the inventor.' 35 U.S.C. § 202(d).

[73] Although Professor Madey's lawsuit remains unusual, a front-page article in the Wall Street Journal in 2006 projected more legal disputes between universities and faculty in the future as universities become more business-like in their management of research on campus, intervening more in decisions about research rather than deferring to faculty autonomy. Bernard Wysocki, Jr., *Ivory Power: Once Collegial, Research Schools Now Mean Business—Arizona State Strips Professor of Empire as Funding Ebbs; Lawsuit Claims Retaliation—A Price on Lab Space*, WALL ST. J., May 4, 2006, at A1.

and social norms interact.[74] In the past decade the biomedical research community has taken numerous measures to fortify its sharing norms in the face of perceived incursions of conflicting incentives to protect and enforce intellectual property.[75] These measures have had some success in influencing the behavior of universities as licensors of patents,[76] but they have been less successful in influencing the behavior of scientists as providers of research materials and data. If anything, it appears that restrictions on dissemination of these 'practically excludable' resources are becoming more common over time,[77] suggesting that sharing norms may be weakening.

If there is indeed an 'ignore patents' norm within the scientific community that serves to forestall potential anticommons problems arising from a proliferation of patents in biomedical research, it might make sense to adjust the patent laws to reflect that norm rather than relying upon noncompliance and nonenforcement under the current law. Widespread disregard of patent laws in respectable institutions like universities threatens to engender disrespect for the patent laws, to the detriment of patent owners. If you live in a community in which patent infringement is pervasive, practiced on a regular basis by all of your competitors and collaborators, when the occasional outlier (such as duPont) decides to enforce a patent, the patent laws seem arbitrary and unfair.[78] If the proliferation of patent rights has led to widespread patent infringement by academic scientists, it is worth considering whether patent owners would be better served by a patent system that drew boundaries that prestigious institutions, such as universities, could respect and abide by.

[74] Fiona Murray & Scott Stern, *Learning to Live with Patents: Assessing the Dynamic Adaptation to the Law by the Scientific Community* (Working Paper 2008), available at <http://imio.haas.berkeley.edu/WilliamsonSeminar/murray041708.pdf>.

[75] See, eg, Dep't of Health & Human Serv., Nat'l Inst. Of Health, Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090 (Dec. 23, 1999); NATIONAL RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY (1997); BOARD ON LIFE SCIENCES, NATIONAL RESEARCH COUNCIL, SHARING PUBLICATION-RELATED DATA AND MATERIALS: RESPONSIBILITIES OF AUTHORSHIP IN THE LIFE SCIENCES (2003); California Institute of Technology et al., *In the Public Interest: Nine Points to Consider in Licensing University Technology* (March 6, 2007), available at <http://www.aau.edu/research/TechTransfer_Pts_to_Consider.pdf>.

[76] See Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31, at 32, 38–39 (2006).

[77] See Cohen & Walsh, *Real Impediments*, n. 7 above, at 118 (comparing their results to those of earlier studies).

[78] An obvious parallel is the widespread disregard of the copyright laws by young music listeners. Sporadic enforcement efforts by the recording industry have been largely ineffective, and have failed to arrest the decline in respect for the copyright laws. See Yuval Feldman & Janice Nadler, *The Law and Norms of File Sharing*, 43 SAN DIEGO L. REV. 577 (2006). Perhaps copyright owners would be better served by a narrower set of rights that were more widely respected. Cf. Mark F. Schultz, *Fear and Norms and Rock & Roll: What Jambands Can Teach Us About Persuading People to Obey the Copyright Laws*, 21 BERKELEY TECH. L.J. 651 (2006) (describing norms against copying that are widely respected within the jamband community).

III. Conclusion

Over the past decade, empirical studies have investigated whether a growing number of intellectual property claims have caused a tragedy of the anticommons in biomedical research. Surveys of scientists suggest that it is rare for an ongoing project to be stopped because of patents. Within the academy, scientists generally ignore patents and rarely face patent enforcement. Perhaps this reflects the continuing vitality of sharing norms in academic science, or perhaps patent owners conclude that enforcement of patents against academic researchers is not worth the cost. On the other hand, scientists report more problems in gaining access to 'practically excludable' resources such as tangible materials and data that they cannot readily duplicate in their own laboratories.

These results point to an important qualification of the anticommons hypothesis. As framed by Heller & Eisenberg, the risk of underuse in an anticommons arises when too many property rights lead to excessive transaction costs and risks of bargaining failures. But bargaining and transaction costs do not always precede the use of resources that are protected as property. Sometimes, as in the case of patents, the burden of inertia is on the owner of the property right to detect violations of its rights and sue for infringement. In this context high transaction costs make enforcement less likely, and unauthorized use more likely, mitigating the risk of an anticommons. On the other hand, when it is easy for owners to exclude users from access to resources, as in the case of 'practically excludable' materials and data, the burden of inertia is on users to persuade owners to permit access, whether or not the resource is covered by formal property rights such as patents. In this context high transaction costs make use less likely, aggravating the risk of an anticommons. The burden of inertia might sometimes be adjusted in the design of legal rules, offering another mechanism for calibrating the balance between the costs and benefits of property rights.